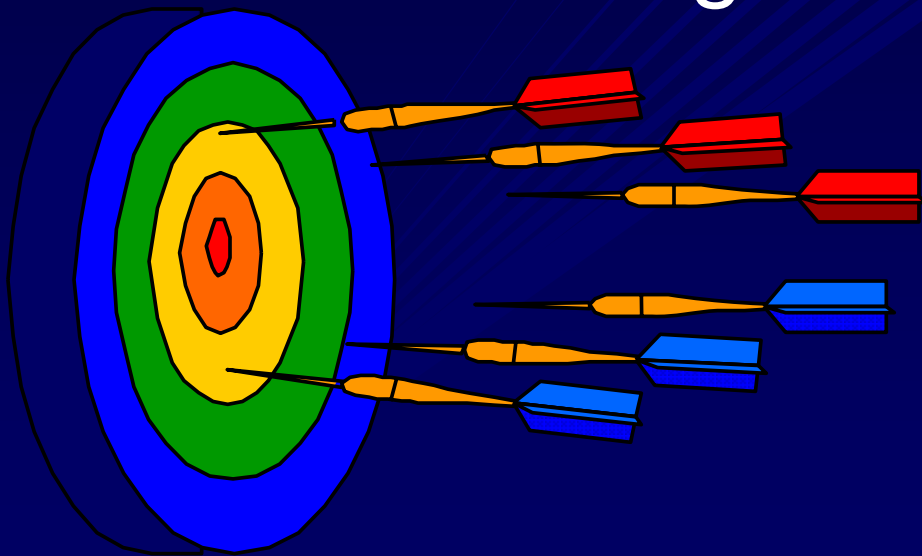


Quality Assurance and National Standardization

Programs For Densitometry
Around the World



Didier Hans

Geneva University Hospital, Switzerland

Outline

- Common features of QA programs
- National Programs Reviewed
 - France
 - Brazil
 - Canada
 - USA
- Challenges, barriers and potential solutions



Why have National QA standards?

- To ensure BMD measures are consistent across a country even for different manufacturers
- To give bone densitometry centers more credibility to referral physicians and to patients
- To ensure that centers work under the most recent and recognized standards of quality
- To validate and endorse the %CV, CVs and LSC for each approved center.
- For radiation safety!

QA / QC in Bone Densitometry

- **Quality Assurance (QA)**

A framework of guidelines, performance goals, quality control tests and preventive measures to assure adequate instrument performance and correct diagnostic assessments.

- **Quality Control (QC)**

Tests to verify adequate diagnostic quality, e.g.

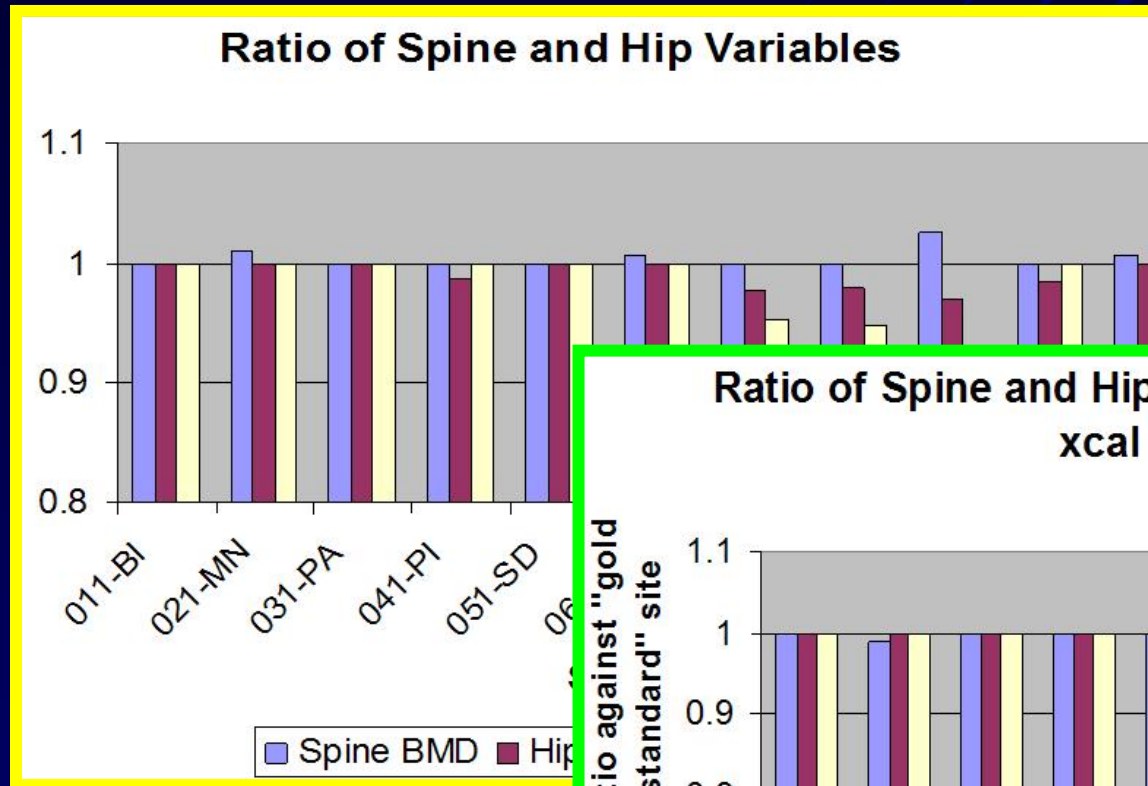
- proper instrument performance
- correct analysis of patients' results

Components of a National QA Program

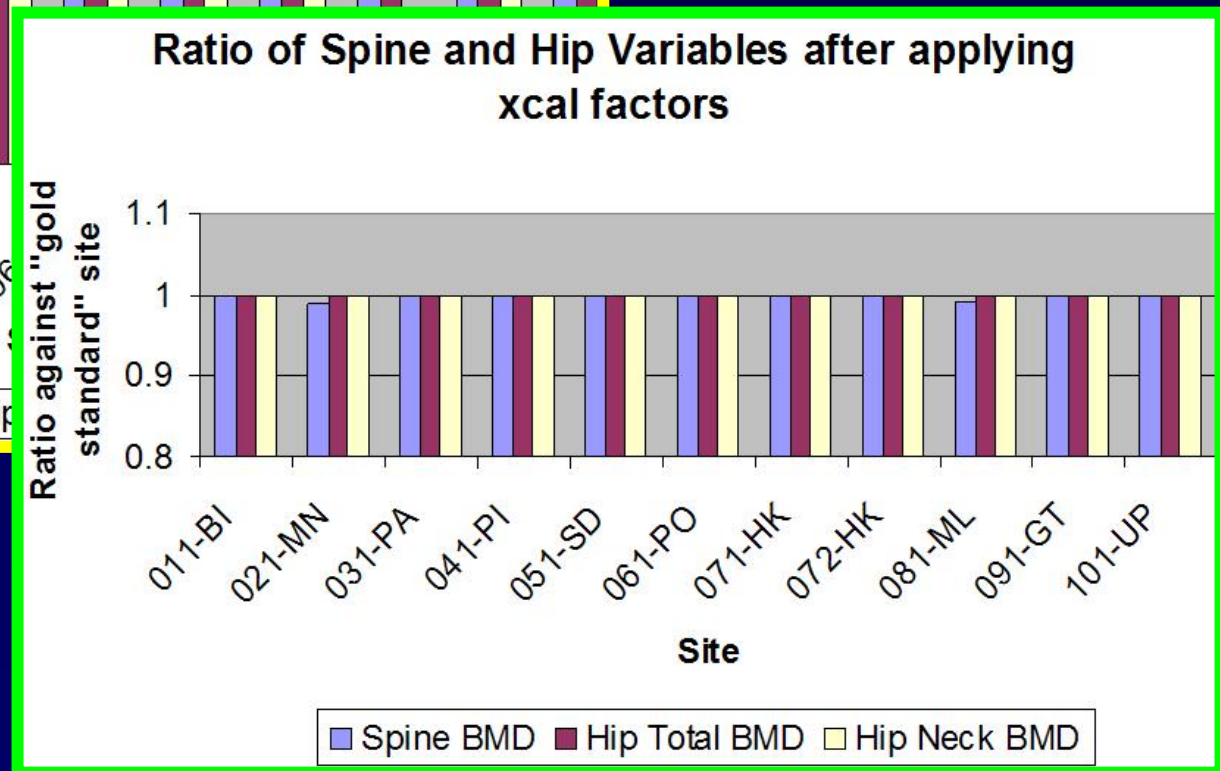
- A centralized QA center or procedures
- Cross calibration methods between like machines with common standards
- Longitudinal Correction methods to correct patient data for changes in calibration over time.
- Standardized training.
- Sufficient know-how to interpret the results taking into account the potential pitfalls

Cross Calibration Example: 11 sites

AFTER

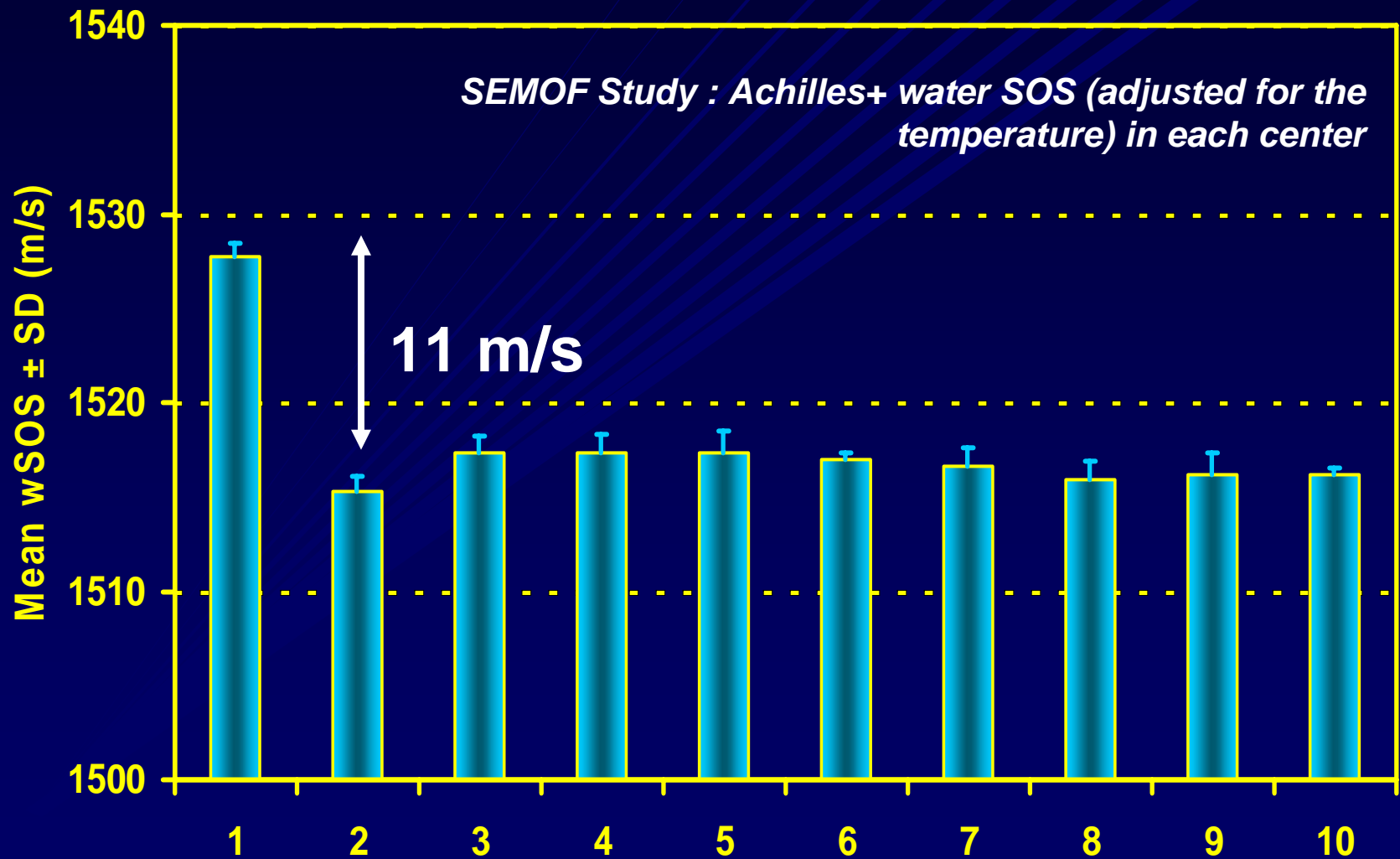


BEFORE



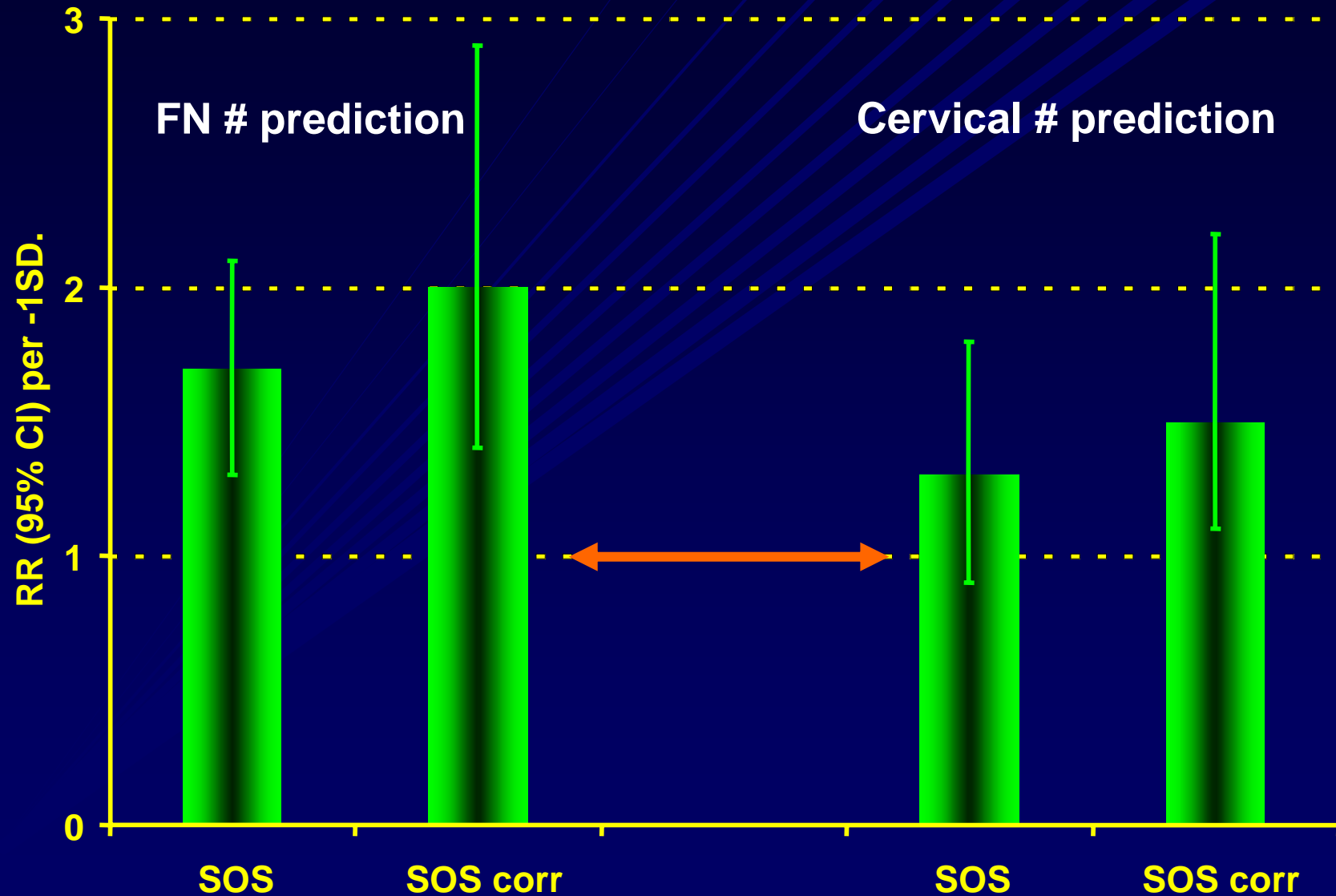
Cross Calibration Example

ACHILLES+ water SOS, by center.



Center From M.A. Krieg et al. J Clin Denistom 2002;5:335-41

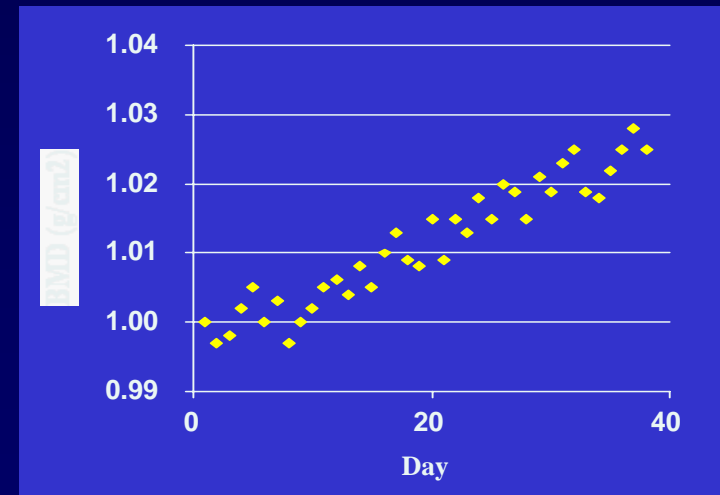
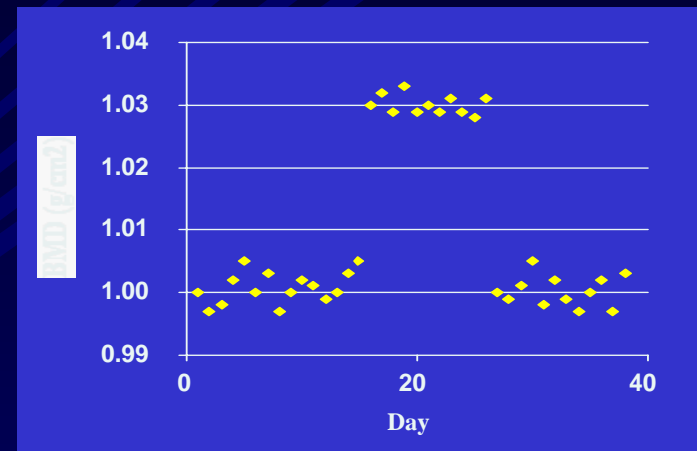
SEMOF study : Prediction of hip fracture risk by Achilles+ SOS in 7609 elderly Swiss women, ± 75 years : effect of correction of SOS on RR



From M.A. Krieg et al. J Bone Miner Res 2002;17(suppl 1):S156

Detecting Changes Over Time

- Calibration **Shift** :
 - maintenance, relocation
 - X-ray tube & detector change
- Calibration **Drift** :
 - gradual changes due to temperature, humidity & power supply
 - Aging of X-ray tube & detector



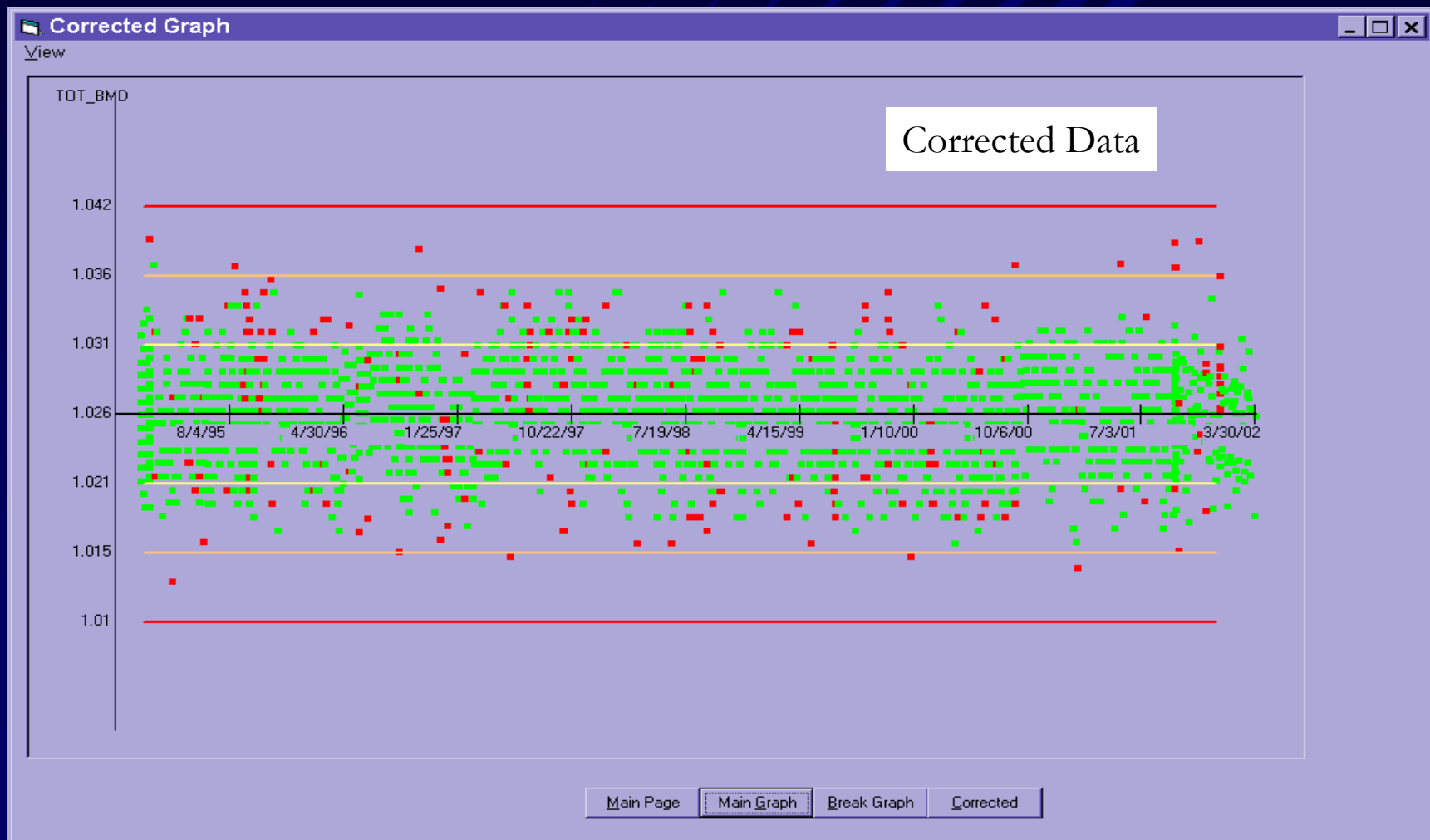
Shewhart Rules

Tests	Pattern Description
1	One point is more than 3 standard deviation from the central line
2	9 points in a row on one side of the central line
5	2 out of 3 points in a row more than 2 standard deviation from the central line
6	4 out of 5 points in a row more than 1 standard deviation from the central line

Cusum Analysis

- Cusum is the cumulative sum of deviations between day value of the phantom and reference value.
- This sum is effective only for significant changes (>0.5 SD). It is expressed in standard deviations (SD).
- The drift of the machine is effective when Cusum is more than 5

Standard Correction Tools: UCSF CUSUM Shewhart Tool



Adapted from J Shepherd presentation

Players in National QA/QC Programs

- Clinics: The bone densitometry clinical centers
- Manufacturers: of densitometry equipment
- QA centers: Act as representatives of the government
- Independent organization ?: Audit, define the procedures etc...



Known QA/QC Programs

- Established

- France
- Brazil



- In Development

- Australia
- Canada
- USA
- China
- Switzerland



French QA and QC procedure for DXA devices

Set-up upon the initiative of the GRIO

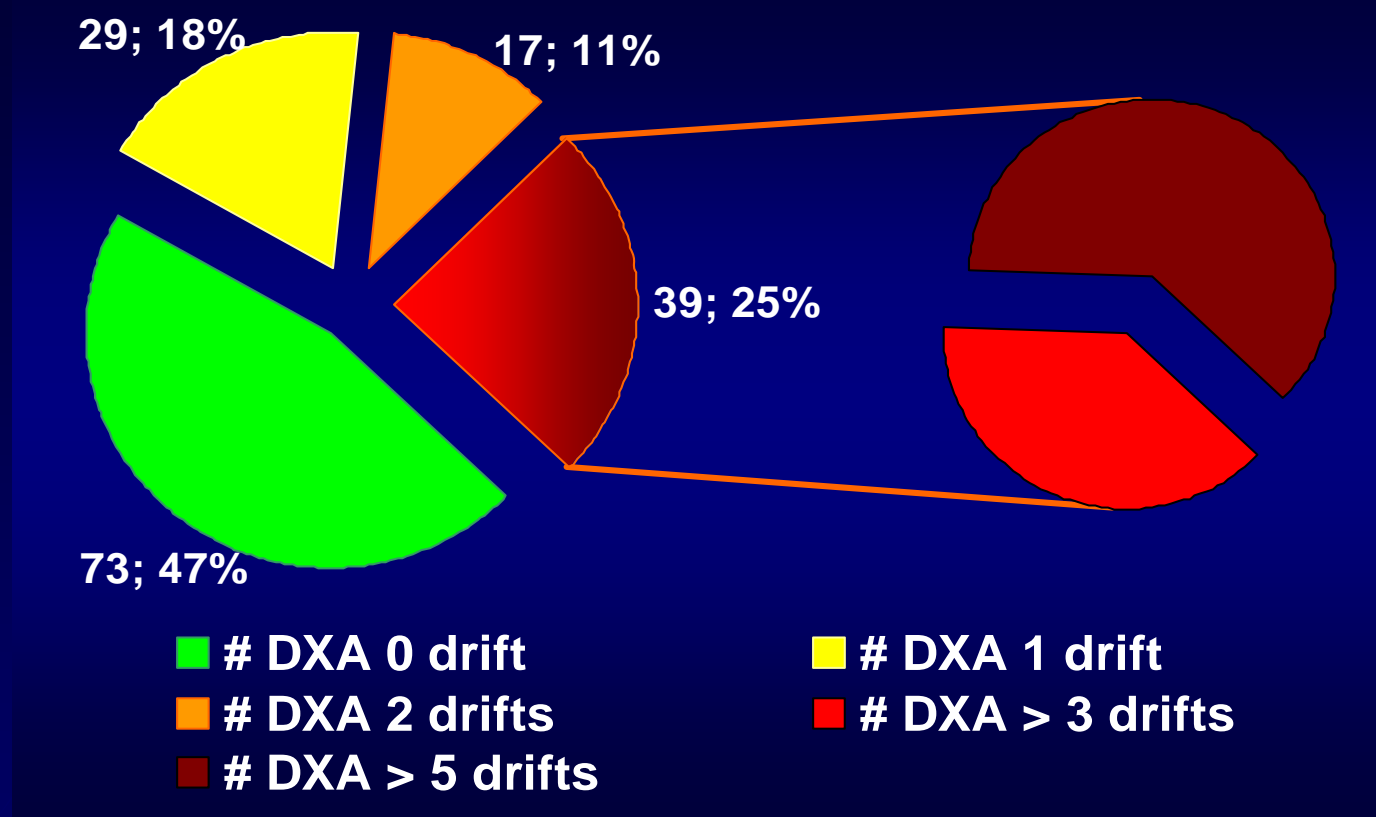


GRIQ Quality Control

- **Consciousness of the necessity of a Centralized Quality Control**
- Define QC procedures with a maximum of applicability to every user without major constraints in clinical routine environment
- **Test the feasibility in 210 clinical centers in France**
- **Final aim:** transfer the know-how to AFSSAPS (Agence Française de Sécurité Sanitaire des Produits de Santé) for a national extension



Results of a 2 years experience



- Nb of regular QC transmissions: 158 out of 210 centers
- 3 types of DXA devices

Adapted from N Barthe, IBDW 2004



French QA/QC



It is the law now...

- Procedures for DXA QC was voted into law in April 2005 by the French government
- Published on June 7th 2005
- Mandatory compliance for reimbursement is set for 1 year, June 2006.



French QC Tasks

- Measurement Tasks
 - BMD accuracy quantification (QA Center)
 - Long term calibration stability (Clinic and QA Center)
 - Radiation dose certification (QA Center)



French QA/QC: BMD accuracy

- **Checking BMD Accuracy:**

- Test with phantom with a BMD close to the T-score = 0 value.
- Measurements done in the presence of the QA center “controller”.

- **Performance Criteria:**

- Acceptability within $\pm 2\%$ or $\pm 3\%$, depending of the model, for the BMD, BMC and AREA
- If outside range: Clinic not certified → service visit before recertification.



French QA/QC: BMD accuracy

- When to check accuracy:
 - For existing systems: within 1 year of Law's implementation
 - For new installations: prior the scanning of patients
 - After each recalibration by the manufacturer



French QA/QC: long term stability

- QA Center provides Clinic dedicated QC software
 - Enter BMD, BMC and Area data
 - Use the Shewhart rules
 - Apply the Cusum
- Establishing Baseline:
 - QA Center Evaluates with their internal software
 - Average of 30 phantom measurements over 30 days
- Baseline Performance Criteria:
 - Average value within $\pm 1.5\%$ of the expected value



French QA/QC: long term stability

After Baseline:

- Clinical Center uses personalized software
- If problem with Shewhart:
 - Violation, rules 2,3,4 or 5 for the BMD, BMC or area: 5 *measurements of the daily phantom within $\pm 1\%$ of the baseline data replace the “erroneous value” previously measured*
 - Violation, rule 1 for the BMD: *repeat the measurement*
- If persistence → DXA device non useable
- If Cusum violation (5) → DXA device non useable



French QA/QC: Radiation Safety



- Performed by QA center
- Performed at baseline, Annually or when major repairs
- Monitors the AP spine mode
- Radiation dose must be within $\pm 20\%$ of baseline value
- If Clinic fails test:
 - 10 days to correct the problem



Brazil – Latin America

ProQuaD®

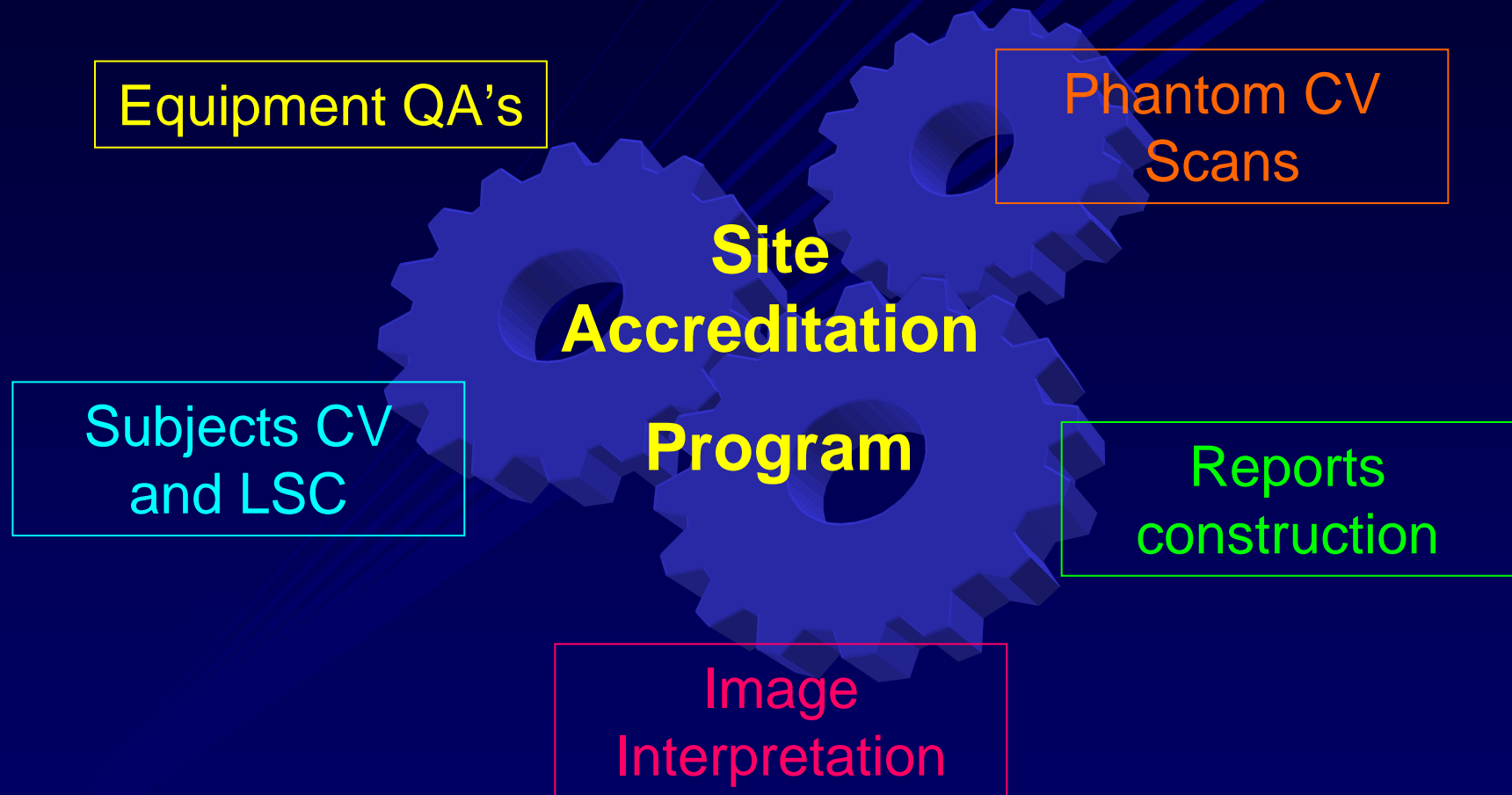
Site Accreditation Program

(Programa Nacional de Qualidade em Densitometria)

More details could be obtained directly at:
proquad@sbdens.org.br



Brazil ProQuaD: Areas of evaluation



ProQuaD program certifies the Densitometry Center e.g Equipment, Tech and Doc (not only the Technologist).

Adapted from Sergio Ragi Eis M.D. C.C.D.



Brazil ProQuaD: First Step

Registration

- Centers invited to participate can access the SBDens web site at www.sbdens.org.br to register.
- **The requirements are the following:**
 - The physician responsible for ProQuaD procedures, should be a Certified Member of SBDens and/or SOLAD and/or ISCD;
 - **Annual dues;**
 - Equipment(s) and software version(s) used be endorsed by SBDens.



Brazil ProQuaD: Download the kit

The “Kit” is, in fact, a ZIP file which contains:

1. ProQuaD Procedures Manual (pdf file);
2. PowerPoint Show with densitometry images (pps file) selected by the ProQuaD committee;
3. Answer Sheets (Word .doc file);
4. Precisa® CV Calculation Software (ProQuaD® user version)



Brazil ProQuaD: Second Step

Procedures for Center to perform:

- 25 Phantom Scans
- **Patient Precision Scans:**
 - 3 scans of 15 subjects OR 2 scans of 30 subjects;
 - Enter results into software provided by the ProQuaD Operational Center (POC);
- **Review the training course and answer questions.**

QA Center Analysis

- LSC, CV, and CV% for phantom and patient scans are calculated
- **Test Graded**



Brazil ProQuaD: Certification

Densitometry Center is Certified if:

- %CV not larger than 1.5% for phantom scans;
- CV, CV% and/or LSC below a predefined threshold (currently, CV% of 4.5%)
- shows a “Good QC File” with less than 3 “fail” registries within the last 3 months
- Passes test with 70% of the questions/test cases correct
- Approved centers are eligible to put ProQuaD stamps in the DXA reports.



Canada

Standards and Guidelines for Performing Central Dual X-Ray Densitometry

(from the Canadian Panel of ISCD)



Canadian QC/QA

Standards "...to establish the minimum level of acceptable performance for the practice of bone densitometry in Canada..."

- Guidelines are extensive, but are not policies enforced by law
- No established methods for certifying sites to be compliant to these guidelines
 - *Postmenopausal Women* - A. Khan, et al. 2002. JCD 5(4):435-45.
 - *Premenopausal women, men, children* - A. Khan, et al. 2003. JCD 51-64.



United States

In progress upon the initiative of ISCD



US QA/QC

- There are no QC/QA standards mandated by law
- International Society for Clinical Densitometry (ISCD) has published guideline position
<http://www.iscd.org/Visitors/positions/official.conf>



US QA/QC Criteria

- ISCD Site Certification under development
- To become accredited, sites will have to demonstrate compliance with ISCD established standards for the following criteria:
 - Personnel
 - DXA Site Quality Assurance (QA)
 - Instructions Prior to DXA
 - Scan Acquisition and Analysis
 - Interpretation
 - Ethics, Business and Regulatory Issues



Independent QA/QC
Standard
for Every Nation?

What can we observe ?



Not very
efficient and is
it necessary?

Some complementarities of each QA programs

Critical Challenges for setting up a QA program

1. Have working procedures which take into account device' diversities and underlying algorithms → standardization ?
2. Have the right phantoms for the right sites ?
3. Simplicity over complexity → Compliance ?
4. Relevance over simplicity → level of expertise ?



Critical Challenges for setting up a QA program (2)

- 5. establish action' criteria to prevent from excessive interventions
- 6. **Motivation and acceptability → mandatory**
- 7. Role of each parties ?
- 8. Associated cost → no reimbursement of DXA in some countries



Potential Solutions to Problem

- **Procedures...**
 - not reinvent the wheel → dedicated working group involving the different players to define the key components of a light but relevant QA program → to do list
- **Phantoms**
 - further development in collaboration with manufacturers
- **Time consuming**
 - QC software integrated into the DXA software
 - Website
- **Motivation**
 - mandatory by law / insurance



Potential role for NIST

- There may be a role for coordinating QA/QC efforts from the NIST to unify standards across national boundaries.
- Facilitate cooperation between manufacturers and research group
- Help cover some of the costs for the needed developments
- Possible intermediary with other interested government agencies
 - IAEA (International Atomic Energy Agency) will host a QA workshop that includes bone densitometry in Vienna next November 2006



Conclusion

It is crucially needed to have a National QA/QC program



It is urgent to define ourselves the best QA program based on scientific evidences and taking into account the clinical routine load before to have it imposed by non experts